DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service d1971b

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012
Telephone:425-486-8788
FAX: 425-483-4996

COPY

July 30, 1998

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-15

Robert Mannix, Hospital Administrator
St. Elizabeth Hospital
3325 Pocahontas Road
Baker City, Oregon 97814

WARNING LETTER

Dear Mr. Mannix:

Your facility was inspected on July 21, 1998 (inspection ID 1778810004) by a representative of the State of Oregon radiation control program, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

1. The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [redacted]

2. The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms: [redacted]

In addition, to the Level 1 findings, several other noncompliances were noted. These include:

Level 2

3. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months: [redacted]

4. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [redacted]

5. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [redacted]

6. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [redacted]

7. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [redacted]

8. The radiologic technologist did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [redacted]

Level 3 Repeats

9. The chest wall edge of the compression paddle was visible on the collimation test image obscuring part of the area of the clinical interest: [redacted]

Level 3

10. For items listed below, the need for corrective action was indicated on the QC records/charts but the execution of corrective actions was not documented (on at least one occasion). SCREEN FILM CONTACT.

11. For items listed below, QC records/charts were present but reflected that the listed tests were not conducted at the proper frequency. SCREEN FILM CONTACT.

12. Processor QC; 22 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing (month of December) [redacted] Room Id = Darkroom.

13. Mammograms were processed at least once with the medium density or density difference or base + fog out of control: [redacted] Room Id = Darkroom.

14. Documentation was missing from the quality assurance (QA) program. The missing QA items are listed below: PERSONNEL RESPONSIBILITIES.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;
- suspend or revoke a facility's FDA certification for failure to comply with the Standards;
- seek an injunction in Federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the Level 1, 2, and 3 repeat violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the non-compliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to Richard S. Andros, Compliance Officer, P.O. Box 3012, Bothell, Washington 98041-3012. Also, send a copy to the state radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Sincerely,

Roger L. Lowell
District Director
Seattle District Office

cc: Robert Rapcinski
Oregon Health Division
800 NE Oregon Street, Room 290
Portland, Oregon 97232-2162

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091